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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/362,485	07/28/99	FLOHE	L 29473/35834

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EXAMINER	
JOHANNSEN, D	
ART UNIT	**PAPER NUMBER**
1655	17

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/362,485	Flohe et al
Examiner	**Art Unit**
Diana Johannsen	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Jun 27, 2001* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) ☐ they raise the issue of new matter. (See NOTE below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: *See Attachment.*

4. ☐ Applicant's reply has overcome the following rejection(s):

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance ~~because:~~
for the reasons set forth in the Attachment to this Advisory Action and for the reasons of record in view of the non-entry of Applicants' After Final amendment.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: *none*

   Claim(s) objected to: *none*

   Claim(s) rejected: *1*

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

11. ☐ Other:

ATTACHMENT TO ADVISORY ACTION

New issues raised.

1. Applicants' proposed amendments raise the following new issues under 35 U.S.C. 103 that would require further search and consideration. Applicant has proposed amending claim 1 so as to require a nucleic acid "consisting of" a DNA sequence selected from SEQ ID NOs 11-25 and sequences "hybridizable therewith" under conditions of "annealing 2 minutes at 69°C and extension 3 minutes at 72°C at a 1.5 mM concentration of $MgCl_2$". As claim 1 previously encompassed nucleic acids comprising the recited SEQ ID NOs and nucleic acids "hybridizable therewith under stringent conditions", Applicants' proposed amendments raise the new issue of whether nucleic acids consisting of the particular SEQ ID NOs recited in the claim and nucleic acids hybridizing thereto under the recited conditions are obvious. Consideration of this issue would require, e.g., consideration of what the art discloses and suggests regarding nucleic acids consisting of the particular subsequences of the molecule taught by Andersen et al recited in proposed claim 1. Further, it is noted that absent a showing of unexpected results with probes that consist of particular subsequences of a gene sequence known in the art (e.g., the L-alanine dehydrogenase gene sequence taught by Andersen et al which comprises each of SEQ ID NOs 11-25), such probes are considered to be functionally equivalent for, e.g., detection of the gene, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have prepared fragments of the nucleic acids of, e.g., Andersen et al, because such fragments would have been useful as probes.

Claim Rejections - 35 U.S.C. § 112

2. With respect to the rejection of claim 1 as containing subject matter which was not described in the specification, it is noted that Applicants' proposed amendment to claim 1 deleting "stringent conditions" and reciting particular conditions would be sufficient to overcome the new matter rejection relating to the recitation "stringent conditions". However, the amendment of claim 1 to delete "set" and insert therefore "diagnostic kit" would be insufficient to overcome the new matter rejection of record, and would necessitate a new rejection under 35 U.S.C. 112, first paragraph. In the response of paper no. 16, Applicants again argue that the specification provides basis for "combinations of the enzyme test kit and a nucleic acid primer consisting of a DNA sequence set forth in claim 1". However, Applicants arguments are not persuasive. First, with respect to page 36, lines 12-15 of the specification, it is noted that the specification refers to "detection of AlaDH activity or....amplification" of the gene. Accordingly, while this teaching provides basis for performing one method or another method, it does not provide basis for a kit comprising both enzymatic detection reagents and nucleic acids. Second, with respect to page 37 lines 5-6, where the specification states that "The disclosure also includes all conceivable combinations of the individual features disclosed", it is noted that the instant specification does not in fact disclose a kit comprising nucleic acids. Particularly, the specification discloses an "enzymatic test kit" (see, e.g., p. 2), and discloses oligonucleotides, primers, and a "DNA sequence" selected from those recited in the present claim (see, e.g., pages 4, 14, and 26); however, a kit comprising the nucleic acids of claim 1 is never described. Accordingly, the

present claim would not constitute a "conceivable combination" of the features of the invention, as nucleic acids present in a kit, container, etc., were never disclosed. Further, with respect to claims 14 and 15 as originally filed, it is noted that claim 14 provided a further limitation of the type of sample to be "used" in different methods, while claim 15 required the use of additional reagents in different methods. The claims do not, e.g., provide that the two methods be combined in some manner into a single method, but merely indicates that the same type of sample/reagents may be employed in each method. While it is acknowledged that the enzymatic and nucleic acid based methods described in the specification share a common objective, the two methods are patentably distinct in that they require distinct and different method steps. There is no disclosure in the specification of a single method in which all of the steps are carried out or in which all of the reagents of the product of claim 1 are employed, or of a single method employing a combination of these two methods. While the responses states that "the original claims set forth a written description of a combination of the enzymatic kit of original claim 1 and the DNA components of original claim 9 to yield the diagnostic kit of present claim 1", such a kit comprising "DNA components" was never disclosed (see discussion above). It is further noted that claim 1 is drawn not to a method, but to a product. No such product was described or discussed in the originally filed specification. Further, the specification does not disclose any other product or entity that could be considered equivalent to the product of claim 1 (e.g., the specification does not refer to a composition, a container, a kit, etc., or to any other product or

combination of products, including all the components now set forth in claim 1). Accordingly, the specification does not provide basis for the product of claim 1.

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday from 7:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at 703/308-1152. The fax phone number for the Technology Center where this application or proceeding is assigned is 703/305-3014 or 305-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana Johannsen

July 18, 2001

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER